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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 601

[Docket No. 97N–0165]

Regulations Requiring Manufacturers to Assess the Safety and Effectiveness of New Drugs and Biological Products in Pediatric Patients; Technical Amendment

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule; technical amendment.

SUMMARY: The Food and Drug Administration (FDA) is amending the biologics regulations to reincorporate a regulation that was inadvertently omitted. This action is being taken to improve the accuracy of the regulations.

DATES: This rule is effective [*insert date of publication in the* **Federal Register**].

FOR FURTHER INFORMATION CONTACT: Stephen M. Ripley, Center for Biologics Evaluation and Research (HFM–17), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852–1448, 301–827–6210.

SUPPLEMENTARY INFORMATION: FDA has discovered that an error has caused an omission in the agency's codified regulations for part 601 (21 CFR part 601). In the **Federal Register** of May 17, 1999 (64 FR 26657), FDA published a final rule that inadvertently omitted § 601.37 when subpart D was revised. Accordingly, § 601.37, which was added in the **Federal Register** of December 2, 1998 (63 FR 66672), is being reincorporated into the regulations and redesignated as § 601.28. In addition, FDA is removing subpart B and reorganizing subpart C in part 601. Accordingly, current § 601.28 is redesignated as § 601.15. This document corrects those errors. Publication of this document constitutes final action under the Administrative Procedure Act (5

NCR 1

U.S.C. 553). FDA has determined that notice and public comment are unnecessary because this amendment is nonsubstantive.

List of Subjects in 21 CFR Part 601

Administrative practice and procedure, Biologics, Confidential business information.

Therefore, under the Federal Food, Drug, and Cosmetic Act, and the Public Health Service Act, and under authority delegated to the Commissioner of Food and Drugs, 21 CFR part 601 is amended as follows:

PART 601—LICENSING

1. The authority citation for 21 CFR part 601 continues to read as follows:

Authority: 15 U.S.C. 1451–1561; 21 U.S.C. 321, 351, 352, 353, 355, 360, 360c–360f, 360h–360j, 371, 374, 379e, 381; 42 U.S.C. 216, 241, 262, 263; sec. 122, Pub. L. 105–115, 111 Stat. 2322 (21 U.S.C. 355 note).

§ 601.12 [Redesignated to subpart C]

2. Section 601.12 *Changes to an approved application* is redesignated from subpart B to subpart C.

Subpart B [Removed and Reserved]

3. Subpart B is removed and reserved.

Subpart C—Biologics Licensing

4. The heading for subpart C is revised to read as set forth above.

§ 601.28 [Redesignated as § 601.15]

5. Section 601.28 is redesignated as § 601.15 in subpart C, and a new § 601.28 is added to subpart C to read as follows:

§ 601.28 Annual reports of postmarketing pediatric studies.

Sponsors of licensed biological products shall submit the following information each year within 60 days of the anniversary date of approval of the license to the Director, Center for Biologics Evaluation and Research:

(a) *Summary.* A brief summary stating whether labeling supplements for pediatric use have been submitted and whether new studies in the pediatric population to support appropriate labeling for the pediatric population have been initiated. Where possible, an estimate of patient exposure to the drug product, with special reference to the pediatric population (neonates, infants, children, and adolescents) shall be provided, including dosage form.

(b) *Clinical data.* Analysis of available safety and efficacy data in the pediatric population and changes proposed in the labeling based on this information. An assessment of data needed to ensure appropriate labeling for the pediatric population shall be included.

(c) *Status reports.* A statement on the current status of any postmarketing studies in the pediatric population performed by, or on behalf of, the applicant. The statement shall include whether postmarketing clinical studies in pediatric populations were required or agreed to, and

if so, the status of these studies, e.g., to be initiated, ongoing (with projected completion date), completed (including date), completed and results submitted to the biologics license application (including date).

Dated: 9/29/00
September 29, 2000.

William Hubbard

William K. Hubbard,
Senior Associate Commissioner for Policy, Planning, and Legislation.

[FR Doc. 00–???? Filed ??–??–00; 8:45 am]

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